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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,470	03/18/2004	Henrik Stender	58576 (48497)	7227
21874	7590	10/13/2006		
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205				
			EXAMINER MYERS, CARLA J	
			ART UNIT 1634	PAPER NUMBER

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/804,470	STENDER ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This action is in response to the amendment filed July 31, 2006. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

2. The examiner reviewing your application at the PTO has changed. To aid in correlating papers in this application, all further correspondence regarding this application should be directed to examiner Carla Myers.

### ***Election/Restrictions***

3. This application contains claims 22-38 are drawn to an invention nonelected with traverse in the response filed February 3, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### **Maintained Rejections**

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-21 are indefinite over the recitation of "wanted and unwanted." "Wanted and unwanted" are not art recognized terms to describe particular nucleic acid

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sequences. Because "wanted and unwanted" have not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to nucleic acid sequences, one skilled in the art cannot determine the meets and bounds of the claimed invention.

Claims 1-21 are indefinite over the recitation of "closest." "Closest" is not art recognized terms to describe the placement of moieties on two probes that hybridize to one another. Since "closest" is a relative term, it is unclear as to whether closest is defined in reference to the location of the moieties (e.g., whether the moieties are immediately adjacent to one another), or in reference to a particular position in the probe. Because the term "closest" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to nucleic acid sequences, one skilled in the art cannot determine the meets and bounds of the claimed invention.

**Response to arguments:**

In the response filed July 31, 2006, Applicants did not specifically address these rejections. Accordingly, the rejections are maintained and made final.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 12, 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller (U.S. Patent No. 5,532,129) in view of Elsas (U.S. Patent No. 6,207,387).

This rejection was set forth on pages 4-8 of the Office action of May 1, 2006 and is maintained for the reasons stated therein.

**Response to arguments:**

In the response filed July 31, 2006, Applicants traversed this rejection. The traversal is on the grounds that neither Heller nor Elsas teaches a method "wherein the presence or amount of wanted DNA or RNA present in the sample can be positively correlated with the fluorescence of the fluorophore of probe A." It is asserted that Heller relies on FRET technology to detect a particular target nucleic acid and that both Heller and Elsas rely on FRET between donor chromophores. The response argues that the present invention does not require FRET technology to detect the "wanted target" of

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SEQ ID NO: 1. Rather, in the instant invention FRET is used to increase the performance of SEQ ID NO: 1 by masking the signal of unwanted targets.

This argument has been fully considered but is not persuasive. The instant claims as broadly written encompass the use of the same FRET technology taught by Heller and Ellas to detect a specific target nucleic acid. In combination, Heller and Ellas teach a method requiring the use of two probes, wherein one probe is complementary to a wanted nucleic acid sequence and the second probe is complementary to an unwanted nucleic acid sequence and wherein the fluorescence emitted from the probe complementary to the wanted nucleic acid sequence is detected as indicative of the presence of the wanted nucleic acid in a sample. Applicants are arguing limitations that are not recited in the claims because the claims do not require a method in which FRET technology is used only to increase the performance of SEQ ID NO: 1 (wanted target). That is, the claims do not specifically recite an active process step or any other limitation wherein the signal generated by hybridization of a probe to unwanted sequences is masked, so that the "performance" of a probe complementary to wanted targets sequences is increased.

The response further argues that Elsas does not describe the use of a probe which increases the specificity of an assay by preventing signal evolution from the unwanted target. This argument has also been fully considered but is not persuasive because it is not directed to limitations recited in the claims. The present claims require only a step of detecting hybridization of probe A to the target sequence wherein the presence of wanted DNA or RNA in the sample **can be positively correlated** with the

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fluorescence of the fluorophore of Probe A. The claims do not require a step in which a probe is used to increase the specificity of the assay by preventing signal evolution from unwanted nucleic acid targets. Further, it is a property of the method of Heller in view of Elsas that the signal generated by the allele specific probe A can be detected and that the fluorescence generated by allele specific probe A can be positively correlated with the presence of wanted nucleic acids in the sample.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller in view of Elsas and further in view of Meade.

This rejection was set forth on pages 8-11 of the Office action of May 1, 2006 and is maintained for the reasons stated therein.

**Response to arguments:**

In the response filed July 31, 2006, Applicants traversed this rejection for the same reasons discussed in paragraph 5 above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

7. Claims 2-11 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller in view of Elsas and further in view of Oliveira, GenBank Accession No. S83568 and Hogan (WO0066788).

This rejection was set forth on pages 11-20 of the Office action of May 1, 2006 and is maintained for the reasons stated therein.

**Response to arguments:**

In the response filed July 31, 2006, Applicants traversed this rejection for the same reasons discussed in paragraph 5 above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

Further, the response argues that the methods of Oliveira are distinct from the claimed invention. This argument is not persuasive because Oliveira was not relied upon alone for its teachings of a method of using two probes to detect a target nucleic acid. Rather, the rejection is based on the combination of teachings of Oliveira and Heller, Elsas, Hogan and GenBank Accession No. S83568.

The response also argues that Oliveira teaches away from the claimed invention because the reference teaches that the probe is specific but cross hybridizes with *S. schleiferi*. It is asserted that those of skill in the art, including Oliveira, were unable to generate a 100% specific PNA probe (for FISH) despite their efforts.

These arguments have also been fully considered but are not persuasive because again the rejection is not based on the teachings of Oliveria alone, but on the stated combination of references. As discussed in the rejection, Elsas teaches a method in which allele specific probes are generated wherein the probes are able to distinguish between nucleic acids containing a single nucleotide mismatch. The cited prior art also teaches the differences between the *S. aureus* and *S. schleiferi* sequences. Accordingly, when taken collectively, the combined references would have lead the ordinary artisan to probes which could distinguish *S. aureus* nucleic acids from *S. schleiferi* nucleic acids. Further, it is noted that the present claims do not require a probe that is 100% specific.



**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers  
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CARLA J. MYERS  
PRIMARY EXAMINER